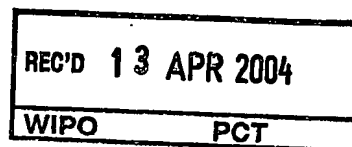




Australian Government

Patent Office  
Canberra

I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003905080 for a patent by UNITRACT SYRINGE PTY LTD as filed on 18 September 2003.



WITNESS my hand this  
Fifth day of April 2004

A handwritten signature in cursive script, reading "J. Billingsley".

JULIE BILLINGSLEY  
TEAM LEADER EXAMINATION  
SUPPORT AND SALES

**PRIORITY  
DOCUMENT**  
SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH RULE 17.1(a) OR (b)

BEST AVAILABLE COPY

P/00/009  
Regulation 3.2

AUSTRALIA

---

*Patents Act 1990*

---

## **PROVISIONAL SPECIFICATION**

**Invention Title: "SYRINGE SPRING RETAINER II"**

**The invention is described in the following statement:**

TITLE

## SYRINGE SPRING RETAINER II

FIELD OF THE INVENTION

THIS INVENTION relates to a spring retainer for a syringe. More particularly, this  
5 invention relates to a spring retainer for a single-use, retractable syringe that  
facilitates prevention of syringe and/or needle re-use

BACKGROUND OF THE INVENTION

The problems of shared syringes are notorious. The practice of sharing  
syringes without adequate sterilisation between successive users is a major  
10 contributor to the transfer of Human Immunodeficiency Virus and Hepatitis with  
subsequent severe repercussions for the sufferer of such diseases and at a high cost to  
society of supporting and providing medical attention to those sufferers.

A lesser but still significant risk associated with unclean needles and syringes  
arises from the possibility of inadvertent needle-stick injuries. This is particularly a  
15 problem for law enforcement officers and paramedics who often encounter users of  
illegal drugs in their professional activities. Additionally, the habits of illegal drug  
users are such that dangerous by-products of their activities, such as discarded  
syringes, are often left in places of public access presenting a risk to the users of  
areas such as public parks and school grounds.

20 International Publication WO 01/80930 describes a single-use retractable  
syringe that is highly effective in preventing syringe re-use by ensuring full  
depression of the plunger during fluid delivery and by ensuring permanent  
withdrawal of the needle by the plunger back into the syringe barrel. In particular,  
retractable syringes such as described in International Publication WO 01/80930,

Australian Patent 731159 and United States Patent 6,083,199 employ a spring to facilitate needle retraction and thereby prevent syringe re-use.

However, resistance by the spring during plunger depression provides an undesirable "feel" to some syringe users, such as intravenous drug users.

5

#### SUMMARY OF THE INVENTION

Therefore, in a broad form the present invention provides a spring retainer for a syringe that provides efficient retraction of a spent needle into the barrel of a retractable syringe while also having improved tactile properties to a syringe user.

10 In one aspect, the invention provides a spring retainer for a syringe having a barrel and a plunger, in use said spring retainer located externally of said barrel and in a slidable relationship with said plunger.

In another aspect, the invention provides a spring retainer for a syringe having a barrel and a plunger comprising at least one shoulder, said spring retainer comprising a housing and a spring compressed therein, said at least one shoulder of  
15 said plunger engageable with said housing to trigger withdrawal of said plunger by decompression of said spring.

In yet another aspect, the invention provides a syringe having a spring retainer according to any of the aforementioned aspects.

20 Preferably, said spring retainer comprises a spring and a housing, in use located externally of said barrel and in slidable relationship with said plunger.

Preferably, in use said housing retains said spring in a compressed state.

Suitably, the syringe has a retractable needle.

Preferably, the syringe has a retractable needle that can be engaged by said plunger to facilitate retraction of the needle.

A preferred embodiment of a retractable single use syringe contemplated for use with the spring retainer of the present invention is described in International Publication WO 01/80930, which is incorporated herein by reference.

5 In a preferred embodiment, said syringe is a retractable syringe having a retractable needle, in use said spring is compressed in said retainer until at or near completion of depression of said plunger to inject material from said syringe, said compressed spring acting thereafter to facilitate withdrawal of said retractable needle.

Throughout this specification, unless otherwise indicated, "comprise", "comprises" and "comprising" are used inclusively rather than exclusively, so that a  
10 stated integer or group of integers may include one or more other non-stated integers or groups of integers.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will now be described with reference to the embodiments disclosed in the accompanying drawings, wherein:

15 FIG. 1 is a perspective view of a retractable single use syringe;

FIG. 2A and 2B are exploded perspective views of a plunger and a first body portion of spring retainer housing;

FIG. 3 is an exploded perspective view of spring retainer and plunger;

FIG. 4 is another exploded perspective view of spring retainer and plunger;

20 FIG. 5 is a cross-sectional view of spring retainer and plunger;

FIG. 6 is another cross-sectional view of spring retainer and plunger; and

FIG. 7 is a top view of second body portion of spring retainer comprising outer ramps.

### DETAILED DESCRIPTION OF THE INVENTION

In FIG. 1 and FIG. 2 is described an embodiment of a single use retractable syringe 10 comprising in part, components based on those originally described in International Publication WO 01/80930. Syringe 10 has plunger 11, barrel 12 and retractable needle 13. Plunger 11 includes first slot 14, second slot 15, retraction slot 16 and fourth slot 17. First slot 14 is interconnected to second slot 15 via first deviation 18, second slot 15 is interconnected to retraction slot 16 via second deviation 19, retraction slot 16 is interconnected to fourth slot 17 via third deviation 20 and fourth slot 17 is interconnected to first slot 14 via fourth deviation 21. First slot 14 and retraction slot 16 are longitudinally offset with respect to each other; second slot 15 and fourth slot 17 are longitudinally offset with respect to each other; first deviation 18 and third deviation 20 are longitudinally offset with respect to each other; and second deviation 19 and fourth deviation 21 are longitudinally offset with respect to each other; as indicated by arrows in FIG. 2. Retractable needle 13 engages plunger 11 by way of needle-engaging means 22 at needle end 23 of plunger 11. Examples of needle-engaging means are also described in Australian Patent 731159 and United States Patent 6,083,199, each of which is incorporated herein by reference. It will also be appreciated that plunger 11 may also employ one or more abutments 25 and/or gates 24 in one or more of slots 14, 15, 16, 17 to co-operate with projections 33A, 33B to assist prevention of syringe re-use, such as shown in FIG. 1 and FIG. 2 and in the manner described in International Publication WO 01/80930.

Referring specifically to FIG. 2, there is shown first body portion 41 of spring retainer 40 having first projection 33A and second projection 33B that respectively engage slots as in FIG 2A or as in FIG. 2B.

Referring now to FIGS. 3 and 4, spring retainer 40 comprises first body portion 41 and second body portion 42 that when fitted together house spring 50. First body portion 41 comprises base 43 having first plunger aperture 44 that slidably accommodates plunger 11. Plunger 11 has shoulders 60A, 60B respectively having tapered surfaces 61A, 61B. Although shoulders 60A, 60B are not shown in FIG. 1 or FIG. 2, it will be appreciated that the portion of plunger 11 having shoulders 60A, 60B in FIG. 3 would be located distal to needle-end 22 of plunger 11 in FIGS 1 and 2.

Again referring to FIG. 3, second body portion 42 comprises second plunger aperture 45 that slidably accommodates plunger 11. Second body portion 42 also comprises shoulder ramps 48A, 48B and shoulder recesses 49A, 49B.

First body portion 41 and second body portion 42 are fitted together on plunger 11 to compress spring 50 by engaging guides 46A, 46B in sidewall 70 of second body portion 42 with respective tabs 47A, 47B of first body portion 41 and rotating first body portion 41 relative to second body portion 42. Guides 46A and 46B have reduced-width portions 80A, 80B and increased-width portions 81A, 81B, the latter permitting limited rotation of first body portion 41 relative to second body portion 42 by approximately 5 to 20°, notwithstanding engagement of tabs 47A, 47B when retainer 40 is assembled. When retainer 40 is assembled, second body portion 42 is also capable of limited, longitudinal or telescopic movement relative to first body portion 41 against the action of compressed spring 50. Typically, this movement is limited to 0.1 to 1.0 mm, preferably to about 0.2 to 0.8 mm or advantageously to about 0.5 mm, although this is readily varied according to the length and/or volume of the syringe, plunger and/or spring.

Referring to FIG. 5 and FIG 6, spring retainer 40 is mounted to barrel 12 at plunger end 51 with first projection 33A and second projection 33B of first body portion 41 engaging slots in plunger 11. In the embodiments described in FIG 6, barrel 12 is integrally formed with finger grips 71A, 71B and housing 72 into which is fitted retainer 40, such as by interference fit with first body portion 41 as shown in FIG. 5.

Rotation of plunger 11 during syringe filling, injection and needle retraction may best be understood with reference to FIG. 2 and International Publication WO 01/80930

Initially, in use, first projection 33A is located in fourth slot 14 and second projection 33B is located in second slot 16. Projections 33A, 33B may be in the form of "fingers" that engage slots 14, 15, 16 and/or 17

In an alternative embodiment, projections 33A, 33B may be spherical or approximately so, to thereby smoothly, slidably engage slots that are appropriately configured to receive such spherical projections.

Withdrawal of plunger 11 is followed by first projection 33A slidably moving from first slot 14 into second slot 15 via first deviation 18 and second projection 33B slidably moving from retraction slot 16 into fourth slot 17 via third deviation 20. This causes a 90° rotation of plunger 11 with respect to barrel 12.

During withdrawal of plunger 11, shoulders 60A, 60B are free to slidably travel through respective shoulder recesses 49A, 49B in second body portion 42.

Depression of plunger 11 to inject or expel material from barrel 12 occurs when first projection 33A is slidably located in second slot 15 and second projection 33B is slidably located in fourth slot 17.



During depression, spring 50 remains compressed by retainer 40 and only towards the end of depression of plunger 11 do shoulders 60A, 60B of plunger 11 engage shoulder ramps 48A, 48B to move second body portion 42 longitudinally to further compress spring 50. This is accompanied by plunger 11 engaging retractable  
5 needle 13. It is noted that tapered surfaces 61A, 61B of respective shoulders 60A, 60B ensure only "last-minute" engagement of shoulder ramps 48A, 48B at the very end of plunger 11 depression.

This, together with the tendency for plunger 11 to rotate a further 90° through first projection 33A moving into retraction slot 16 via second deviation 19 and  
10 second projection 33B moving from fourth slot 17 via fourth deviation 21 into first slot 14, acts to rotate second body portion 42 relative to first body portion 41. This rotation aligns respective, reduced-width portions 80A, 80B of guides 46A, 46B with respective tabs 47A, 47B to allow tabs 47A, 47B to slide out of engagement therewith thereby allowing spring 50 to decompress and, in turn, forcing  
15 disengagement of second body portion 42 and first body portion 41. This force is relayed to plunger 11 by second body portion 42 bearing against shoulders 60A, 60B of plunger 11 thereby facilitating retraction of plunger 11 and attached needle 13.

It will therefore be apparent from the foregoing that it is only at the very end of plunger depression that decompressed spring 50 acts in facilitating plunger 11 and  
20 needle 13 withdrawal. This provides a much smoother feel to the operation of the syringe without any significant spring resistance being felt during most stages of injection.

Another advantage provided by the spring retainer 40 of the invention is that it can accommodate a spring 50 of various sizes, such as being operable with varying

needle sizes and syringe sizes. In the higher volume syringes with longer needles, the length of spring 50 required to facilitate retraction of plunger 11 may be too great to fit easily on plunger 11 external to barrel 12. Retainer 40 compresses spring 50 into a manageable size irrespective of the uncompressed length of spring 50.

5           With regard to the foregoing embodiments, there may be additional embodiments that facilitate prevention of re-use of syringe 10.

For example, with reference to FIG. 3 and FIG. 4 in particular, shoulders 60A, 60B and second body portion 42 of retainer 40 may be of sufficient length (axially along plunger 11) to prevent rotation of plunger 11 when projections 33A, 33B have  
10       not yet respectively engaged retraction slot 16 and first slot 14 at the start of plunger 11 withdrawal. This assists prevention of a user seeking to rotate plunger 11 back into an operable position before withdrawal has commenced.

In another embodiment shown in FIG. 7, guides 46A, 46B in sidewall 70 of second body portion 42 may include respective outer ramps 85A, 85B. Once second  
15       body portion 42 is disengaged from first body portion 41, it travels axially with plunger 11, driven by decompressed spring 50. According to the embodiment described in FIG. 7, second body portion 42 travels axially until ramps 85A, 85B are respectively engaged by tabs 47A, 47B in first body portion 41 thereby forcing second body portion 42 to rotate, which in turn rotates plunger 11 by virtue of  
20       engagement between shoulders 60A, 60B of plunger 11 and shoulder ramps 48A, 48B of second body portion 42.

By aligning projections 33A, 33B respectively with second deviation 19 and fourth deviation 21 coupled to the rotation of plunger 11 caused by rotation of second

body portion 42, rotation of plunger 11 into its final inoperable position is driven not only by projections 33A, 33B but also by rotation of second body portion 42.

This minimizes the likelihood of a situation where plunger 11 could fail to rotate fully and jam further plunger 11 movement, thereby leaving needle 13 only partially retracted.

Throughout the specification, the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Various changes and modifications may be made to the embodiments described and illustrated without departing from the present invention. In particular, it is contemplated that gates, abutments, ledges and other means disclosed herein for restricting plunger movement may be readily interchanged as desired by the skilled person.

DATED this eighteenth day of September 2003

UNITRACT SYRINGE PTY LTD

by its Patent Attorneys

FISHER ADAMS KELLY

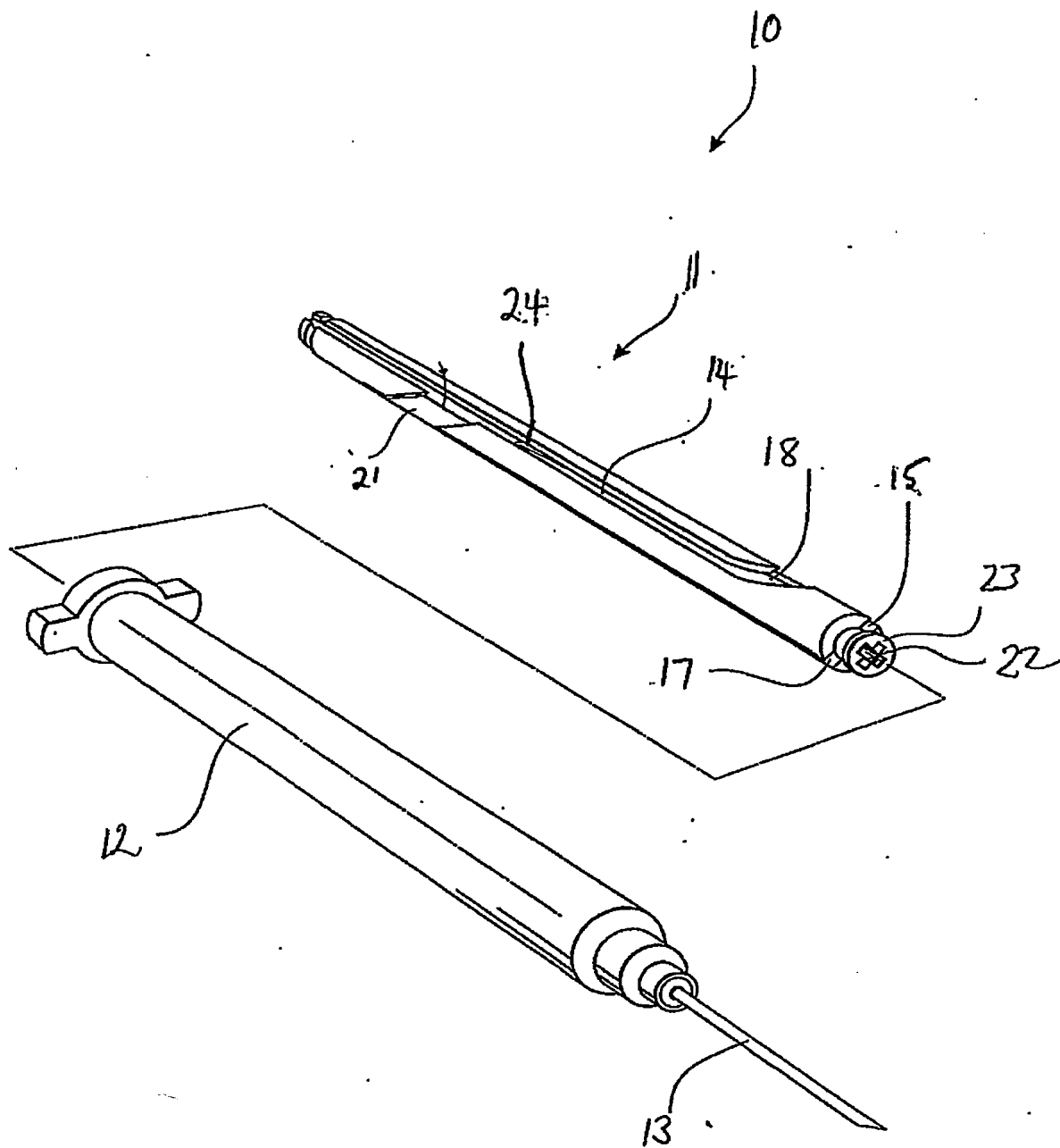
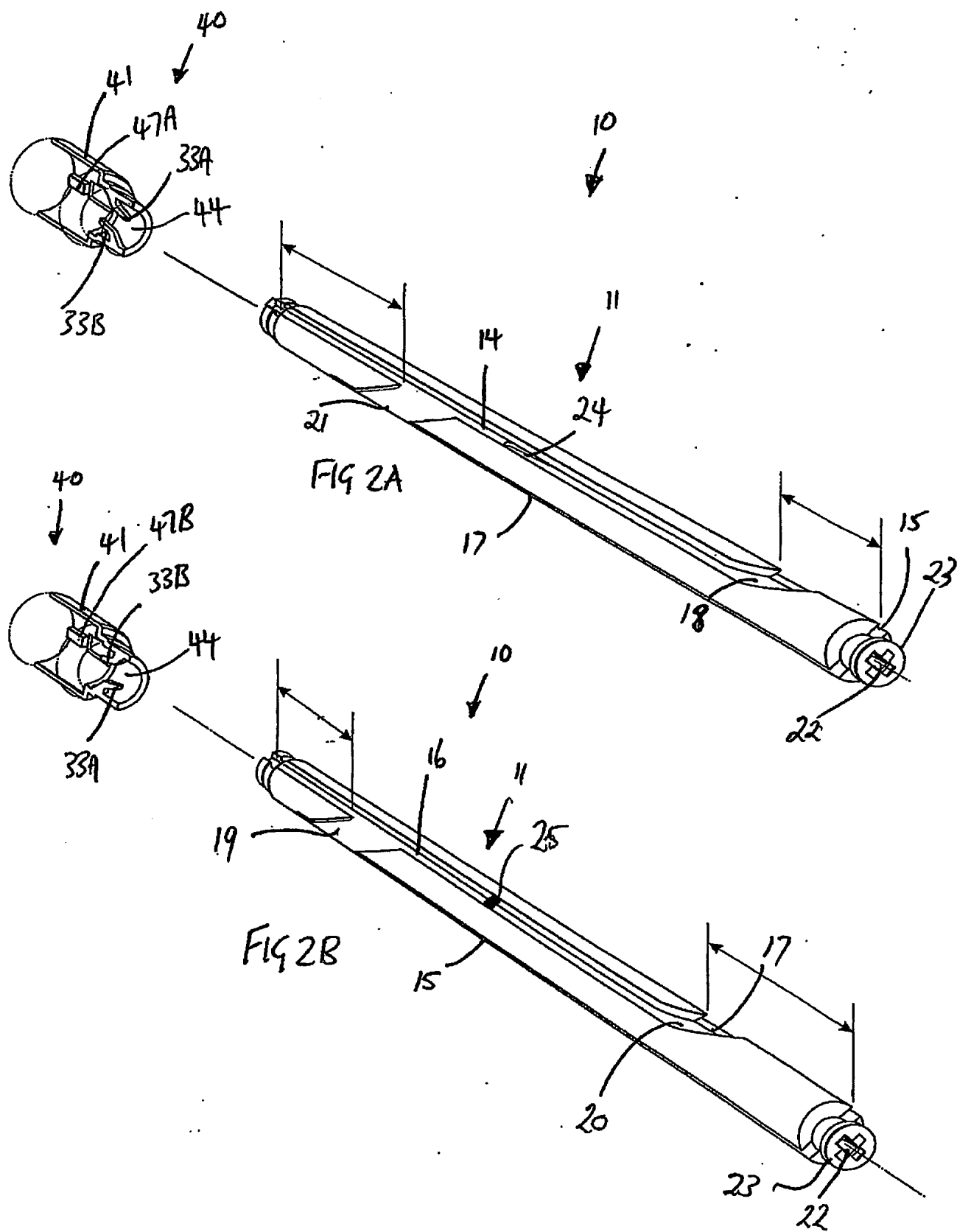


FIG. 1



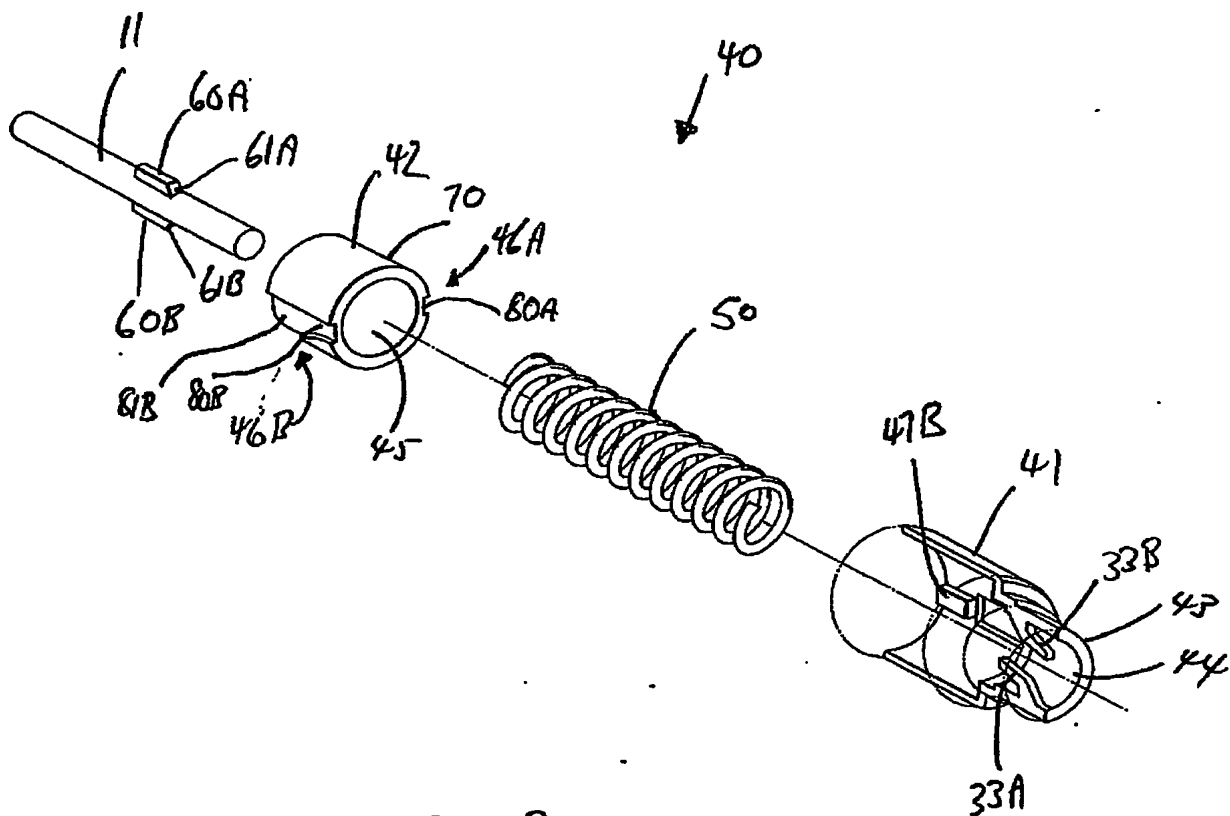


FIG. 3

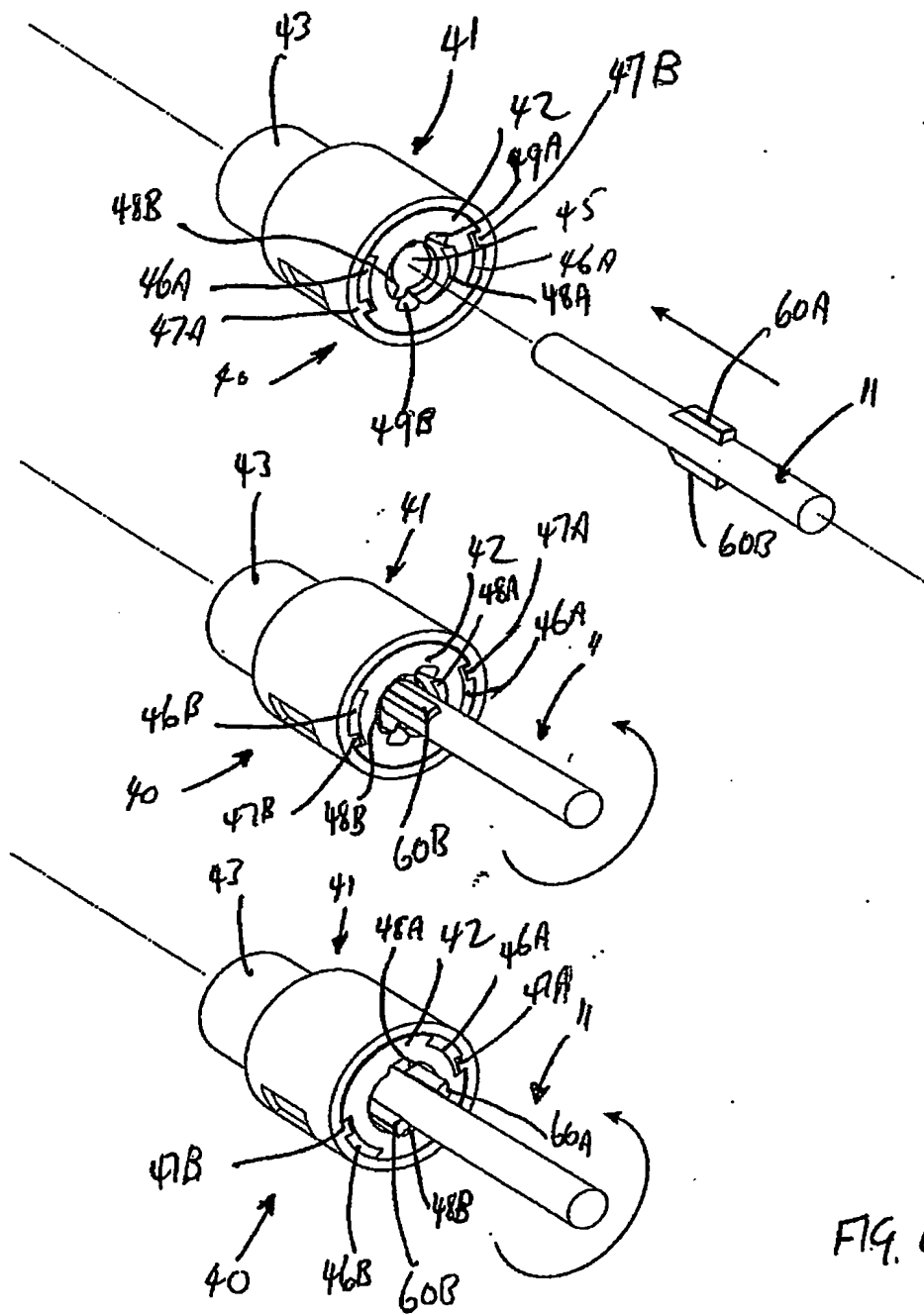


FIG. 4.

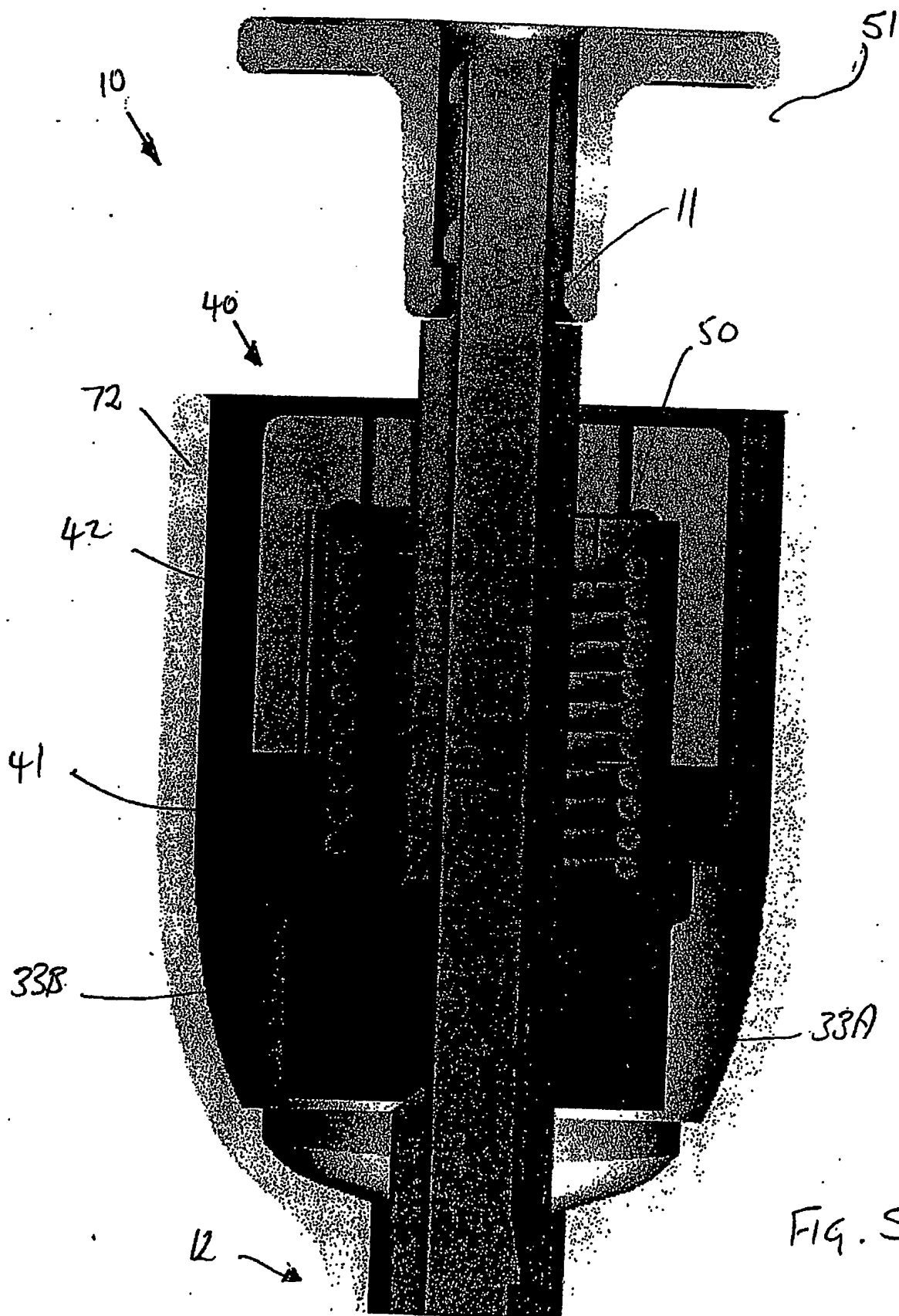


FIG. 5



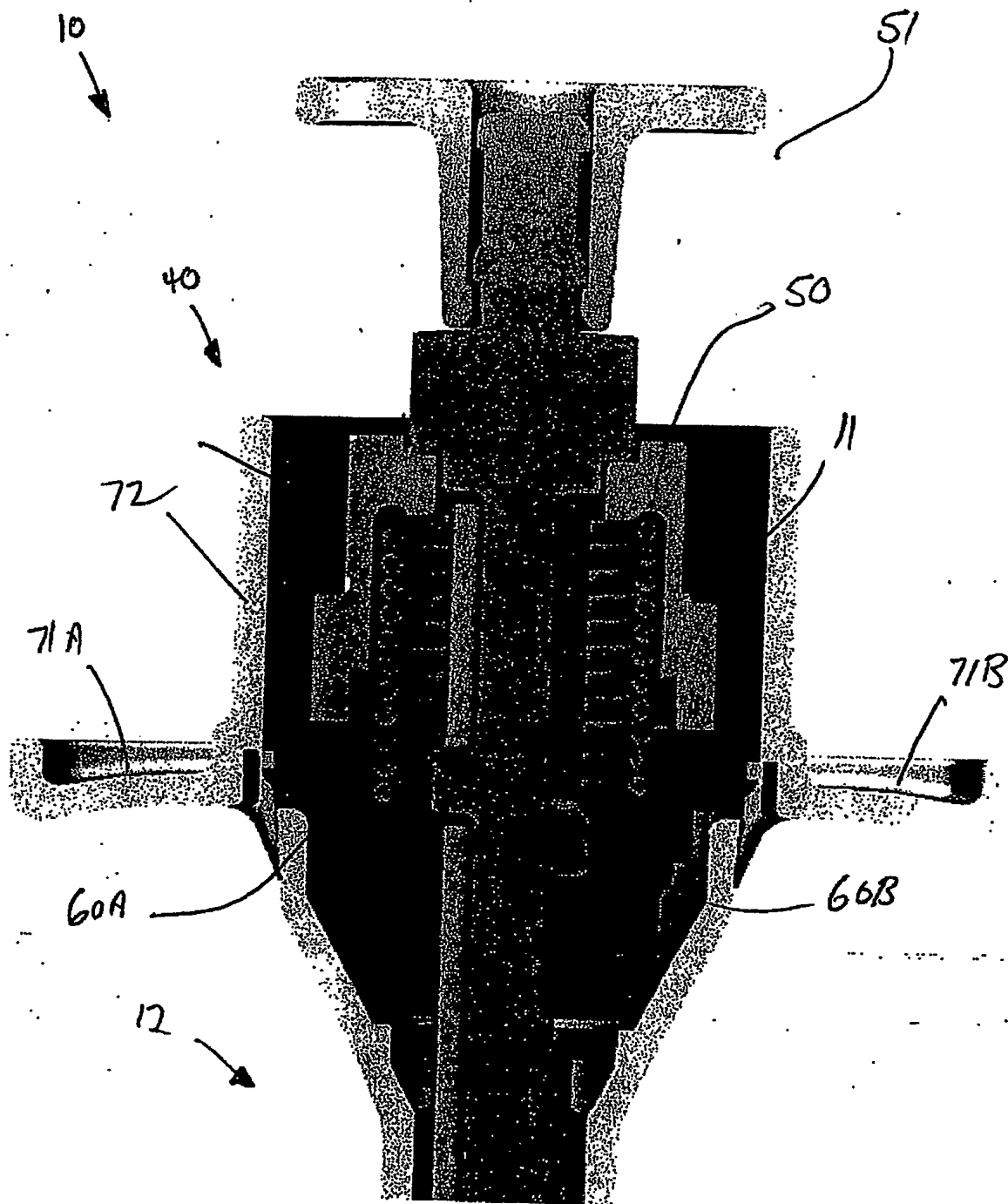
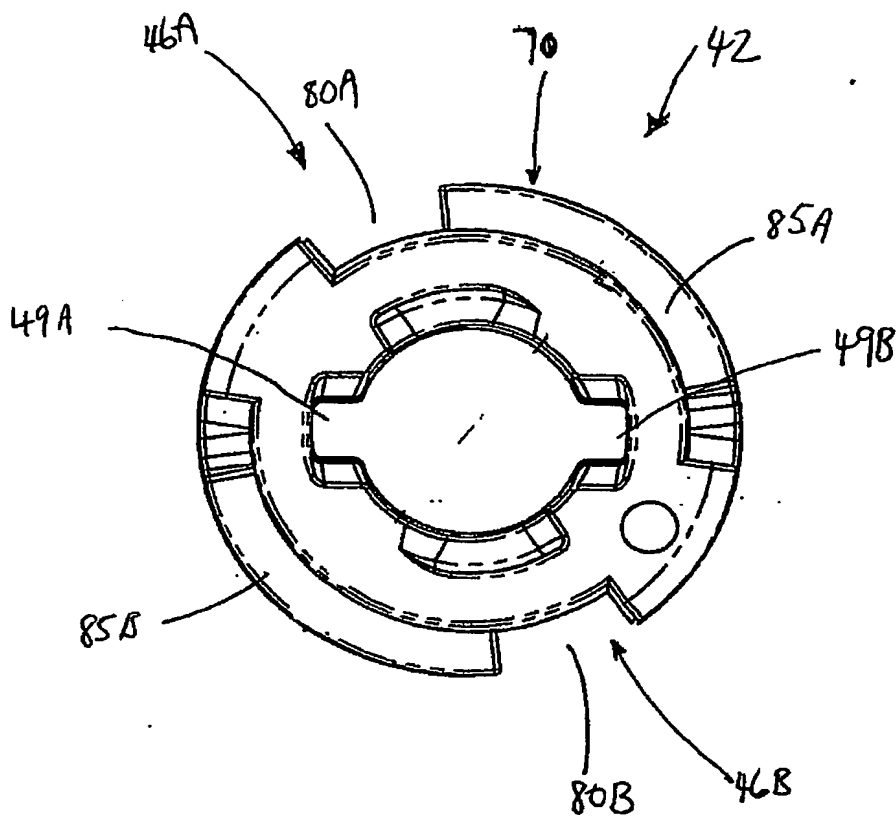


FIG. 6



**FIG. 7**

This Page is inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☒ BLACK BORDERS

☒ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

☒ FADED TEXT OR DRAWING

☒ BLURED OR ILLEGIBLE TEXT OR DRAWING

☐ SKEWED/SLANTED IMAGES

☐ COLORED OR BLACK AND WHITE PHOTOGRAPHS

☐ GRAY SCALE DOCUMENTS

☐ LINES OR MARKS ON ORIGINAL DOCUMENT

☐ REPERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images  
problems checked, please do not report the  
problems to the IFW Image Problem Mailbox**